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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/800,839 03/07/01 SHIMIZU

T 2535US1P

023115 HM22/1002
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EXAMINER

TRAN, S

ART UNIT

PAPER NUMBER

1615

DATE MAILED:

10/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/800,839

Applicant(s)

Shimizu et al.

Examiner

Susan Tran

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1615



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other:

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DETAILED ACTION

Double Patenting

1. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

2. Claims 1-8, and 13-19 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-7, and 13-19 of copending Application No. 09/403,429 (The constructively elected invention is drawn to a non-enteric coated rapidly disintegrable solid preparation. Election was by original presentation see MPEP§818.02(a)). This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim Rejections - 35 U.S.C. § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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Claim 18 is rejected under U.S.C 101 because the claimed invention is directed to non-statutory subject matter. Use claims are not considered to be one of the permitted classes of invention. Applicant should recite a method or process that includes at least one step.

Claim Rejections - 35 U.S.C. § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-7, 9, and 13-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Ohno et al. US 5,958,453.

Ohno teaches a solid pharmaceutical composition in powder or granular that can be made into tablet suitable for buccal administration (column 2, lines 13-61). The composition comprising active ingredient; sugar, e.g., mannitol or erythritol; and disintegrant, e.g., low substituted hydroxypropyl cellulose at about 1-15 parts by weight base on 100 parts by weight of the solid composition (columns 2 and 5). The active ingredient can be selected from various classes that is disclosed in columns 3-4. Column 6, lines 59-67 further teaches the dissolution of the tablet, which can be completely dissolved in about 0.1 to 1.0 minute.

Claim Rejections - 35 U.S.C. § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohno et al.

US 5,958,453, in view of Shashoua et al. US 5,795,909.

Ohno is relied upon for the reasons stated above. In the case the Applicant can overcome the above 102(b) rejection, the Examiner relies upon the following 103(a) rejection. The examiner notes that Ohno is silent as to the teaching of the claimed active ingredients in claims 8, and 10-12.

Shashoua teaches a pharmaceutical composition for oral administration in a tablet form (columns 49-50) comprising active ingredients, e.g., pioglitazone, lansoprazole, candesartan, and manidipine (columns 27, 35, and 41-46). Thus, it would have been prima facie obvious for one of the ordinary skill in the art to modify Ohno's formulation using the active ingredients in view of the teaching of Shashoua. The reason for this modification is to obtain a pharmaceutical preparation having the above active ingredients for oral administration with improved disintegrability and/or dissolubility.

Pertinent Arts

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Makino et al., and Koyama et al. are cited as being of interest for the teaching of quick dissolved tablet.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


THURMAN K. PAGE
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